REMARKS

Status of the Claims

Claims 1, 3, 5-7, 9-15, 17, 19-21 and 46-50 are pending in this application. Claims 2, 4, 8, 16, 18 and 22-45 have been canceled. Thus, claims 1, 3, 5-7, 9-15, 17, 19-21 and 46-50 are presented for examination.

Support for the amendment to claim 1 can be found, for example, in paragraphs [0015] and [0057] of the specification and in original claims 16 and 18. No new matter is added.

Rejection under 35 USC 103(a)

Claims 1, 3, 5-7, 9-21 and 46-50 are rejected under 35 USC 103(a) as being unpatentable over Hossainy et al., U.S. Patent No. 6,153,252 (Hossainy) in view of Bolz, U.S. Patent No. 6,287,332 (Bolz). Applicant respectfully traverses this rejection.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' " *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn* , 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. "When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' … Thus, 'obviousness requires a suggestion of all limitations in a claim.' …" *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

According to the Office Action, Hossainy is deficient in that Hossainy fails to disclose the biodegradable inner core material is specifically selected from biodegradable metallic or ceramic materials. The Office Action, however, turns to Bolz, urging that it would have been

obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz, because doing so would provide mechanical advantages (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.).

The composite device proposed by the Examiner can also be described as the application of polymer coating as described in Hossainy to a biodegradable metallic stent as taught in Bolz.

Regardless, there would be no reason to provide a coating in accordance with Hossainy on a stent in accordance with Bolz, and in fact, there would be reasons *not* to apply such a coating.

In this regard, the primary reason for applying a polymer coating to a metallic stent is to create a reservoir for a therapeutic agent (metals are not typically good reservoir materials). The presently claimed invention, however, is not directed to devices of this type and in fact expressly excludes therapeutic agents.

It is true that another potential function of a polymeric coating would be to regulate the degradation rate of an underlying biodegradable inner core material, and that is in fact the subject matter of the present claims. However, to use applicants invention as motivation would be improper hindsight. See MPEP 2142 ("impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art").

Moreover, Bolz teaches that degradation rate may be controlled using other available methods, specifically: (a) by controlling the ratio of the metallic elements with in an alloy stent. See col. 3, lines 43-44 and (b) by controlling the size of the surface of contact between a substantially pure corrodible stent body (e.g., zinc) and a local electrode connected thereto or by the selection of the element forming the local electrode (e.g., a gold electrode) (in other words, analogous to the principle behind galvanized materials). See Col. 3, lines 36-58 and Example 2. Thus, there is no reason to use a coating for purposes of controlling degradation.

On the other hand, there are reasons to avoid the use of polymer coatings, particularly where there are no compelling reasons to include them in a given device (e.g., therapeutic agent release), including the fact that many polymeric materials are known to induce foreign body responses upon implantation. In this regard, see Willem J. van der Giessen et al., "Marked Inflammatory Sequelae to Implantation of Biodegradable and Nonbiodegradable Polymers in Porcine Coronary Arteries," *Circulation.* 1996;94: 1690-1697 (of record) ("An array of both

biodegradable and nonbiodegradable polymers has been demonstrated to induce a marked inflammatory reaction within the coronary artery with subsequent neointimal thickening…") See also U.S. 4,613,517, which notes at col. 1, lines 20-24, that while polymers may have become preferred materials for prosthetic devices, a major drawback of many of these materials is their thrombogenicity. See further US 2008/0091262. ("Various byproducts of degradation of biodegradable polymers are known to incite an inflammatory response.")

Moreover, even assuming for the sake of argument that a biodegradable polymer can be selected from Hossainy that does not provoke a foreign body response, one would not add a coating of such a material to a biodegradable stent without good reasons for doing so. In this regard, the addition of such a coating would add to manufacturing cost and complexity. Another issue with adding materials to implants, is the fact that such added materials would have to undergo regulatory scrutiny prior to use.

In the Office Action, the Examiner reiterates the argument that it would have been obvious to one of ordinary skill in the art at the time the invention was made to form Hossainy's inner core from a biodegradable metallic material as taught by Bolz, because doing so would provide mechanical advantages such as elasticity, deformability, ductility and tensile strength.

The Examiner further argues that "[t]he burden was placed on the applicant to provide reasons as to why the biodegradable metallic material would not be suitable for use in Hossainy's inner core and that since the applicant failed to provide arguments as to why it would not have been obvious to one having ordinary skill in the art to form Hossainy's inner core from a biodegradable metallic material, it is the Examiner's position that such a modification would have been obvious to one having ordinary skill in the art given the advantages taught by Bolz.

Applicant argument, however, is not that the material of Bolz cannot be used as an inner core material. Rather Applicant's argument is that it would not be obvious to combine the material of Bolz with a biodegradable polymer covering material of Hossainy, especially when that covering material does not contain a therapeutic agent. See above discussion and Hossainy throughout.

For at least the foregoing reasons, the presently claimed invention is patentable over Hossainy and Bolz. Reconsideration and withdrawal of the rejection under 35 USC 103(a) are respectfully requested.

Conclusion

Applicants submit that all pending claims are in condition for allowance. Should the Examiner be of the view that a further interview would expedite consideration of this application, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any issues in this case.

Respectfully submitted,

Dated: January 21, 2011
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